UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BRISTOL-MYERS SQUIBB SECURITIES LITIGATION	:	Civil Action No. 00-1990 (SRC)
	:	Return Date: June 6, 2005
	:	Oral Argument Requested

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE THE EXPERT TESTIMONY OF ROBERT C. NELSON AND RICHARD H. GRIMM

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PRELIMINARY STATEMENT

Lead Plaintiff, the LongView Collective Investment Fund ("Lead Plaintiff"), respectfully submits this memorandum of law in opposition to Defendants' motion to strike, pursuant to Fed. R. Evid. 702 , the testimony of Lead Plaintiff's experts Dr. Robert C. Nelson and Dr. Richard H. Grimm. As more fully set forth below, Defendants seek to strike Dr. Nelson's testimony on a variety of grounds, but somehow fail to note that Bristol-Myers Squibb held Dr. Nelson in sufficient regard to seek his expert advice in early 2000 in connection with its plans for monitoring the safety of Vanlev. Defendants seek to strike portions of Dr. Grimm's testimony even though Defendants' own experts described Dr. Grimm as "probably the world's expert" in estimating the mortality benefits associated with quantified reductions in blood pressure.[1]

Although Defendants fashion their motion as one seeking to strike Dr. Nelson's report and testimony in their entirety, in fact only particular portions of his expert opinions are being challenged. Defendants direct their challenges to the summaries of opinions recited in the introductory section of Dr. Nelson's report, rather than the opinions and analysis he expounds in the body of the report. Attached as Appendix A hereto is a list of Dr. Nelson's opinions that do not appear to be challenged by Defendants on their instant Daubert motion and therefore cannot be excluded. In any event, for the reasons set forth herein, the challenged portions of his report should not be stricken and Dr. Nelson should not be precluded from testifying in this action.

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[1] Lead Plaintiff's expert reports were submitted as exhibits 12-19 to the Declaration of James W. Johnson, Esq. in Opposition to Defendants' Motion for Summary Judgment, dated February 4, 2005. To the extent any exhibits cited herein were submitted in support or opposition to Defendants' summary judgment motion, they will be referred to as either "PX" or "DX" and will bear their original summary judgment reference number. Any new exhibits, which were not submitted either in support of or opposition to Defendants' summary judgment motion, are being submitted herewith as exhibits to the Declaration of James W. Johnson In Opposition to Defendants' Motions To Strike The Expert Testimony of Lead Plaintiff's Expert Witnesses, dated May 23, 2005 ("Johnson Opp. Decl."), and are referred to as "Pl. Opp. Ex. ___."

As to Dr. Grimm's report and testimony, Defendants' motion is expressly directed to limited statements. Most of Dr. Grimm's opinions are not challenged. As discussed below, Defendants' challenges to Dr. Grimm's statements are without merit; his report should be admitted in its entirety and he should be permitted to testify on all the opinions set forth therein.

STATEMENT OF FACTS

Defendants purport to set out the factual background to Dr. Nelson's and Dr. Grimm's testimony, but most of these "facts" are derived from testimony of Defendants' purported experts. (See Memorandum of Law in Support of Defendants' Motion to Strike the Expert Testimony of Robert C. Nelson and Richard H. Grimm ("Def. Mem."), at 2-5.) Lead Plaintiff has challenged much of this testimony, and the facts as stated by Defendants are in dispute.

Dr. Nelson, an epidemiologist, industry consultant and former FDA officer submitted an expert report in this matter addressing usages and customs of the pharmaceutical industry and the FDA with respect to drug safety issues. Dr. Nelson worked for the FDA for 30 years, during which time he held a succession of responsible positions and was instrumental in shaping the agency's policies and standards with respect to drug safety. (Meth Ex. 5 48-92; PX 16 Ex. A.)

In the seven years since he retired from the FDA, Dr. Nelson has consulted for pharmaceutical companies on regulatory science and drug safety issues. (Meth. Ex. 5 22:12-19.) For example, BMS contacted Dr. Nelson to solicit his advice on Vanlev safety issues at around the time the first NDA was being prepared. (Id. 40:13-43:13.) In deposing Dr. Nelson, Defendants' counsel elected not to probe the basis for the many opinions set forth in Dr. Nelson's report, and instead only inquired into the basis for the summaries of opinions set forth in an introductory section of the report for the reader's convenience.

Dr. Nelson has offered expert opinions on regulatory matters in a number of actions. These include a product liability matter, Titus v. Abbott Labs, in which Dr. Nelson submitted an

expert report on behalf of defendant Abbott Labs, and Madden v. Wyeth, another product liability matter in which he testified on behalf of the plaintiff. (Meth Ex. 5 14:25-17:3; 17:10-19:17.) He has also provided expert testimony in personal injury matters involving drug safety, on behalf of both plaintiffs and defendants. (Id. 13:17-14:24.)

Dr. Grimm, recognized internationally as a pre-eminent specialist in hypertension and cardiovascular medicine, with an accomplished record in clinical practice, teaching and clinical research, submitted an expert report opining on good clinical trial practices and standards as those standards can be applied to the case of Vanlev's development. According to Defendants' expert Dr. Elijah Saunders, Dr. Grimm is "probably the world's expert" in estimating the mortality benefits associated with quantified reductions in blood pressure. (Pl. Ex. 11 249:23-250:4.)

Dr. Grimm has served in highly responsible capacities – including principal investigator, steering committee member, and other roles – on many of the most important hypertension trials over the past 30 years, including both NIH-sponsored and industry-sponsored clinical trials. (PX 15 1-2.) He spends about 90 percent of his professional time working on clinical research. (Meth Ex. 4 20:6-13.) Dr. Grimm helped design and carry out "ALLHAT," one of the most significant cardiovascular clinical trials ever undertaken, which studied anti-hypertensive and lipid-lowering therapies in over 42,400 high-risk hypertensives to reduce the risk of heart attack. (Meth Ex. 4 23:24-24:6.) He has extensive experience on data safety monitoring boards for clinical trials. (Meth Ex. 4 40:11-43:6.)

Some of Dr. Grimm's opinions concern the likelihood that doctors would prescribe Vanlev under various scenarios. When Defendants' counsel deposed Dr. Grimm, the examining attorney did not probe the basis for Dr. Grimm's expertise in this subject area. Dr. Grimm's

extensive experience as a top authority in cardiovascular clinical research and treatment encompasses a singular depth of knowledge into the prescribing practices of physicians. Although the expertise on which Dr. Grimm bases these opinions is clear from his CV, a declaration by Dr. Grimm (Pl. Opp. Ex. 11.) recites his qualifications for offering the opinions at issue with the particular detail he was not given an opportunity to elaborate at his deposition.

ARGUMENT

I. Legal Standards Governing Admission of Expert Testimony

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony and provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The rule was amended in 2000 in response to Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and to the many cases applying Daubert, including Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), and General Elec. Co. v. Joiner, 522 U.S. 136, 140 (1997). More recently, in Schneider v. Fried, 320 F.3d 396, 405 (3d Cir. 2003), the Third Circuit described these requirements as the "trilogy of restrictions on expert testimony: qualification, reliability and fit."

Here, Drs. Nelson's and Grimm's respective reports and testimony meet these standards. Neither of the challenged experts should be precluded from testifying to certain matters in this action, because each does possess sufficient knowledge, skill, experience, training or education in his respective field, and each is competent to testify to certain matters under Fed. R. Evid. 702.

Each witness's opinions is reliable, in that they are based upon years of extensive experience and knowledge in their respective fields, and each challenged opinion rests upon a reasoned factual basis and supporting data. In no case does the challenged testimony invade the province of the jury and in all cases it would "assist the trier of fact to understand the evidence or to determine a fact in issue" as required by Rule 702. Finally, none of the testimony is cumulative; therefore, all of it should be admitted.

II. The Challenged Testimony Satisfies the Requirements for Qualification, Reliability and Fit

A. Dr. Nelson is Qualified Under Third Circuit Law on Expert Qualification

It is well settled that in the Third Circuit the "qualification" requirement of Rule 702 is interpreted liberally, such that "a broad range of knowledge, skills, and training qualify an expert." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994) ("Paoli II") (citing In re Paoli R.R. Yard PCB Litig., 916 F.2d 829, 855 (3d Cir. 1990) ("Paoli I")); see also, Parkinson v. Guidant Corp., 315 F. Supp. 2d 754, 758 (W.D. Pa. 2004). It is an abuse of discretion for a court to construe the qualification so narrowly that a competent expert is excluded based on his or her lack of specialization in a particular subfield of the area of competence. See, e.g., Holbrook v. Lykes Bros. Steamship Co., 80 F.3d 777, 782 (3d Cir.1996) (holding that the trial court had abused its discretion in excluding a competent medical doctor from testifying as an expert witness on the plaintiff's diagnosis or a pathology report because he was not a pathologist, oncologist or expert in "definitive cancer diagnosis."); accord, Parkinson, 315 F. Supp. 2d at 758.

Defendants' motion to strike and preclude the testimony of Dr. Nelson (and Dr. Grimm) entirely misreads the applicable case law on qualifications and seeks to disqualify these experts on grounds that they lack very specific areas of knowledge. Defendants' arguments do not warrant disqualification of either of Lead Plaintiff's challenged witnesses; lack of particularized

knowledge or experience is properly considered by the factfinder in weighing the witnesses' testimony. See, e.g., Holbrook, 80 F.3d at 782 ("Because of [the Third Circuit's] liberal approach to admitting expert testimony, most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility. Thus, witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified. Who is 'best' qualified is a matter of weight upon which reasonable jurors may disagree."); Taylor v. Danek Medical, Inc., No. Civ. A. 95-7232, 1999 WL 310647, at *2 (E.D. Pa. May 10, 1999) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are traditional and appropriate means of attacking shaky but admissible evidence.")

1. Dr. Nelson is Qualified to Render the Challenged Opinions and the Testimony Will Assist the Fact Finder in Determining Whether Defendants Departure From Industry Standards Constituted Recklessness

Dr. Nelson is an abundantly qualified expert in drug safety and FDA regulatory process. His expertise spans the full range of issues relating to the identification, evaluation and reporting of drug safety issues in new drug development programs. His professional experience and expertise comprise the application of drug safety principles from the perspective both of a regulator and an industry consultant.

Defendants claim that Dr. Nelson is not qualified to render a number of opinions that they mischaracterize as opinions regarding Defendants' "State of Mind." As set forth more fully below, the bulk of the opinions Defendants challenge under the rubric of "State of Mind" provide necessary guidance for a factfinder to assess whether Defendants' departure from industry standards constituted recklessness. See Point II(C), infra.

Of the so-called "State of Mind" opinions to which Defendants object are those concerning "what BMS knew or should have known about [Vanlev] at various points in time, what BMS knew about [Vanlev] but ignored, and to what extent BMS emphasized the commercial development of [Vanlev] at the expense of good clinical practice and patient safety." (PX 16 1.) Such opinions are offered to inform the jury of standards for good practice within the pharmaceutical industry to assist the factfinder in assessing the questions of whether and to what extent Defendants made statements that were reckless because they embodied an extreme departure from the standards of ordinary care. The same is true of the opinions Defendants categorize as relating to "Probability of FDA Approval," "Regulatory Climate," "Interactions with the FDA," including "what BMS knew or should have known, at various points during the development of Vanlev, concerning the probabilities that the FDA would approve [Vanlev] for various indications." (PX 16 1.) And, contrary to Defendants' representations, the opinions on "Ethics" are similarly opinions on regulatory standards and compliance. Since the opinions are all offered to assist the finder of fact in understanding industry standards and practices, and what knowledge can be imputed to an actor adhering to those standards and practices, Dr. Nelson's qualifications to render all of the challenged opinions are addressed in a single discussion, without respect to the categories Defendants attempt to impose.

All of Dr. Nelson's opinions are well supported by his qualifications as a safety regulator with a 30-year career at the FDA, and as an experienced and accomplished industry consultant on drug safety and regulatory matters. See, Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684, 699-702 (W.D.N.C. 2003). During his tenure at the FDA, Dr. Nelson participated in approximately 500 meetings with drug companies about safety issues, and in the seven years since his retirement from the FDA, Dr. Nelson has been a consultant to the pharmaceutical

industry and related businesses in areas including, but not limited to, drug safety, drug risk assessment and regulatory affairs. (Meth Ex. 5 57:13-14;) Even BMS has recognized Dr. Nelson's qualifications in this respect by requesting his assistance in designing a drug safety surveillance program for Vanlev and other drugs. (Id. 40:13-42:13.)

It is beyond cavil that a former FDA officer is qualified to opine on "how information should be communicated to the FDA and what information should be reflected in labels." In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001). The bulk of Dr. Nelson's testimony relates to the regulatory standards for reporting information to the FDA and for informing study investigators through investigator brochures (which are effectively labels for investigational drugs).

2. Testimony Similar To That Offered By Dr. Nelson Here Has Been Upheld By Courts

The Nelson testimony is of exactly the same nature as that which was upheld on a Daubert challenge in Smith, 278 F. Supp. 2d at 699-702. The Smith decision is instructive and is considered here at some length. The challenged expert Dr. Moye, unlike Dr. Nelson, had never been an employee of the FDA, but he did serve for five years as a member of the Cardio-Renal Advisory Board. Dr. Moye, who was a professor of biostatistics, with qualifications as a medical doctor and extensive clinical trial experience, was permitted to testify on a number of regulatory and safety matters, including "the applicable standard of care for reporting adverse drug events." Id., at 701-02. Dr. Nelson's experience with the FDA and its reporting requirements is far more intensive than was Dr. Moye's. As in the instant case, Dr. Moye's testimony was offered for the purpose of establishing Defendant's knowledge of the risks of at issue. Smith, 278 F. Supp. 2d at 701. The Smith court rejected the defendant's efforts to disqualify Dr. Moye based on hair-splitting points in his qualifications. For example, the court was unmoved by the defendant's

objection that Dr. Moye was familiar only with post-marketing safety reporting requirements, not regulations concerning pre-marketing reporting, in light of Dr. Moye's testimony that "the intent of all of the reporting requirements is essentially the same." Dr. Nelson has reiterated throughout his report and his deposition testimony that his regulatory experience regarding safety relates to pre-marketing as well as post-marketing compounds. (See, e.g., Meth Ex. 5 79:8-82:14.)

Similarly, the Smith court was unpersuaded that Dr. Moye's experience in performing risk/benefit analyses for drugs was not adequate to qualify him as an expert because he did not have experience in performing such analyses with diet drugs specifically. This challenge is similar to Defendants' argument on the instant motion that Dr. Nelson is not qualified to opine on Vanlev's safety because he never served in the Cardio-Renal Division, notwithstanding that his career was dedicated to developing and implementing agency-wide policies concerning drug safety. Defendants' challenge based on the particular job titles Dr. Nelson did or did not hold at the FDA, ignoring the substance of his responsibilities and experience at the agency, should be as unavailing here as the challenge in Smith.

3. Defendants' Reliance on Rezulin and Diet Drugs is Misplaced

As more fully set forth in Point III, Defendants' reliance on In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531 (S.D.N.Y. 2004) ("Rezulin"), and In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000) ("Diet Drugs I") and In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001) ("Diet Drugs II"), is misplaced. The challenged testimony in both Rezulin and Diet Drugs consisted of "inferences about the intent or motive of parties." But Dr. Nelson's opinions do not purport to explain the motivation or understanding of various actors. Instead, the import of Dr. Nelson's testimony is simply to elucidate the standards for good conduct within the industry, a subject

well within Dr. Nelson's area of expertise. Diet Drugs I is further distinguishable in that the experience of the proffered experts did "not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think regarding their non-scientific goals." Diet Drugs I, 2000 WL 876900, at *9. In contrast, Dr. Nelson has vast experience as a consultant to industry in the areas of drug safety and regulatory strategy. These areas plainly involve fine judgments regarding the interplay of safety concerns, marketability and profitability: regulatory approval is not a simple yes/no question, but rather a matter of whether the economically desirable labeling can be achieved, and if not, whether further development of a compound is warranted. Accordingly, regulatory affairs, one of Dr. Nelson's areas of uncontestable expertise, requires an understanding of a company's "non-scientific goals."

4. Dr. Nelson's Testimony Concerning "Ethics" Relates to Industry Standards and is Permissible

Defendants further object to opinions in which Dr. Nelson uses the word "ethics." As an epidemiologist with deep and extensive expertise in drug safety and regulatory practice, Dr. Nelson is eminently qualified to offer opinions on standards and guidelines for human subject research. These industry standards and guidelines, which have been adopted by the FDA, are pillars of the industry standard, and Dr. Nelson is familiar with all of them. That the opinions Defendants characterize as "Ethics" opinions are in fact opinions concerning usage and custom in the pharmaceutical industry is illustrated by the following excerpt from Dr. Nelson's report: "BMS failed to monitor for a predictable toxicity partially due to non-compliance with best practices of new drug development for a NME. Given the knowledge of the mechanism of action and the very early indicators (signals), this corporate behavior deviates from ethically based best practice." (PX 16 37.)

Even where:

> there is no cause of action for breach of an ethical standard of care, testimony regarding ethical duties may be useful in informing the jury about the accepted standards of medical care which a reasonable health care provider would follow and in helping the jury to determine whether Defendants deviated from those standards.

Garcia v. Columbia Med. Ctr. of Sherman, 996 F. Supp. 617, 627 (E.D. Tex. 1998). The opinions Dr. Nelson seeks to offer explain, among other things, how breach of an ethical duty can violate industry usage and custom.[2]

5. Defendants Have Misrepresented Dr. Nelson's Qualifications

It should not go without remark that in the service of their arguments Defendants have seen fit to misrepresent Dr. Nelson's qualifications, as reflected in the record. For example, in expounding their claim that Dr. Nelson is only familiar with post-marketing surveillance, and therefore unqualified to opine on drug safety issues with investigational drugs, Defendants baldly mischaracterize Dr. Nelson's professional experience. For about 30 years, Dr. Nelson held a succession of policy-making positions at the FDA, helping to shape the agency's entire approach to drug safety issues. (Meth Ex. 5 49:24 – 50:7; 51:14-72:4.).) He now offers consulting services in areas in which he considers himself expert. Based upon his qualifications, Dr. Nelson is an expert in both pre-marketing and post-marketing drug safety. (Meth Ex. 5 101:21-24; 102:8-18.)

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[2] Defendants repeatedly and gratuitously point out that he is not a medical doctor. In order to qualify as an expert, Dr. Nelson needs to have "specialized knowledge" regarding his area of testimony. Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000). Dr. Nelson, who has never held himself out to be a medical doctor, does not offer opinions on clinical medicine. His specialized knowledge and experience in drug safety, epidemiology and regulatory affairs qualify him to render his opinions in these areas. In any event, a medical degree is not a sine qua non for competency as an expert in every field with some relation to healthcare or medical science. See, e.g., Diet Drugs II, 2001 WL 454586, at *21-23 (admitting the testimony of a Ph.D. expert about weight loss and reduction of comorbidities associated with obesity, over opponent's objection that the expert has no medical training or expertise in the medical or pharmacological treatment of obesity or its comorbidities).

Any purported distinction between pre-marketing and post-marketing safety regulations was found to be inadequate grounds for disqualifying an expert who had demonstrated familiarity with one but not the other, in Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684, 701-02 (W.D.N.C. 2003). But even if there were a distinction, Dr. Nelson is well qualified to talk about FDA safety standards and procedures for investigational drugs. He has testified as an expert in at least one case in which he opined on the adequacy of material submitted in support of an NDA seeking to make a marketed prescription drug available over-the-counter. As Dr. Nelson explained in his deposition, this material is considered by the FDA to be in the nature of a "pre-marketing" submission. (Meth Ex. 5 17:10-19:17.)

Additionally, his responsibilities at FDA related to both investigational and approved drugs. For example, from about 1986 to 1989 when he served under a succession of position titles in the Office of Biologics Research and Review, Dr. Nelson and his office met with the division directors "on every IND [Investigational New Drug application] and NDA and [went] over the data on everything." (Meth Ex. 5 74:10-12.) As Dr. Nelson testified, decision-making about new drugs is "much more collective than is commonly understood," and as an FDA officer he participated in meetings and discussions, both internally and with the sponsor pharmaceutical companies, where the risks and benefits of new drugs were discussed. (Meth Ex. 5 74:13-22.) This description of the workings of the FDA is entirely consonant with the testimony of Defendants' purported FDA expert Dr. Stephen Fredd, who stated: "The process of the FDA is like the process of a think tank. These are intellectual people looking at data and considering what the data might mean or not mean, and as colleagues we would often discuss things." (PX 26 31:2-6.)

Similarly, Defendants' assertion that Dr. Nelson does not have experience reviewing New Drug Applications ("NDAs") is flatly contradicted by his testimony. During his tenure at the FDA, Dr. Nelson performed some secondary reviews and even medical reviews for some drugs, and additionally had ongoing policy and management oversight responsibility for a range of issues including NDA reviews. (Meth Ex. 5 49:24-50:7; 51:14-72:4.)

Defendants argue that Dr. Nelson should be disqualified from opining on FDA standards and practices as they would have applied to Vanlev because he did not work in the Cardio-Renal Division, which reviewed the Vanlev NDA, or in the Office of Drug Evaluation I, the administrative unit within which the Cardio-Renal Division lies. This kind of hair-splitting over the experience of competent experts is exactly the approach that has been repeatedly rejected by the Third Circuit.[3] (See, e.g., Elcock, 233 F.3d at 741; Holbrook, 80 F.3d at 782; see also, Smith, 278 F. Supp. 2d at 699-702 (rejecting similar challenges by defendants to plaintiff's FDA expert). Dr. Nelson's expertise, in contrast, covers the full range of the FDA paradigm for assessing and responding to safety issues. In any event, there is nothing in the record to suggest that different standards or practices apply to the work performed by the Cardio-Renal Division or the Office of Drug Evaluation I as compared with the FDA offices within which Dr. Nelson worked.

Defendants' claim that Dr. Nelson cannot opine on the FDA regulatory climate during the review of Vanlev because he "was not even at the FDA" during the period in question is completely fatuous and misses the point of Dr. Nelson's testimony. Since leaving the FDA in 1998, Dr. Nelson has worked consistently as a consultant, primarily to industry, in drug safety

[3] In any event, Defendants' FDA expert, Dr. Heidi Jolson, has never worked in the Cardio-Renal Division, and has no familiarity with the regulatory issues surrounding cardiovascular drugs. Under Defendants' standards, their own FDA expert's testimony should be stricken.

and regulatory affairs. In his present business, his up-to-date knowledge about FDA policies and practices is his stock in trade. What Dr. Nelson's opinion offers the trier of fact is not an FDA insider's secret information about what did or did not happen within the FDA, but rather the insight of a regulatory affairs expert into how a reasonable pharmaceutical company would have interpreted public actions taken by the agency in the period of time leading up to the submission and review of the first Vanlev NDA. Accordingly, Dr. Nelson's specialized knowledge as a regulatory and drug safety consultant to industry, and as a former FDA officer, is more than sufficient to qualify him to offer an opinion rebutting Defendants' assertion that the "regulatory climate" suddenly changed during the time when the Vanlev NDA was under review.

There can be no question that Dr. Nelson is fully familiar with the FDA's safety reporting requirements, the contents of an IND application and an NDA, and FDA practices and procedures for reviewing INDs and NDAs, and he is qualified to render each and every one of the opinions in his report concerning regulatory standards and process.

B. Dr. Grimm is Qualified to Render the Challenged Opinions

Defendants claim that Dr. Grimm is not qualified to opine that if FDA had known of the seriousness of angioedema with Vanlev in the First Class Period, it could and would have intervened. But Dr. Grimm is fully qualified, as an eminent clinical trialist, to render the opinion Defendants challenge. As Dr. Grimm states in his report, the FDA has the power to intervene in ongoing clinical development programs to protect patient safety. Dr. Grimm has specialized knowledge of patient safeguards in place in clinical trials, and has served on data safety monitoring boards for a number of major clinical trials. (Meth Ex. 4 20:6-13; 38:16-41:24.)[4]

[4] It is also worth noting that with respect to OCTAVE the FDA effectively did intervene. OCTAVE did not have any morbidity or mortality end points, as is usually the case when a

Similarly, Dr. Grimm's opinions concerning the OCTAVE data from an epidemiological and trial design perspective do not rely upon any specialized knowledge of regulatory process. Dr. Grimm merely explains that the OCTAVE trial design defined the criteria for success or failure of the trial. He further explains that the data that emerged were clearly inconsistent with the hypothesis that Vanlev was comparably safe. The crux of the opinion is that an objective measure was set for the trial's success or failure, and the trial failed; in this case, the failure of the clinical data to support the trial's safety hypothesis was per se a failure to overcome the one obstacle that FDA had identified to the drug's approval. These opinions fall well within Dr. Grimm's expertise in the design and interpretation of clinical trials.

Dr. Grimm's opinion that the OCTAVE data did not satisfy the benchmark set by FDA are based upon his expertise and decades of experience in designing, conducting and interpreting results of clinical trials. His opinion does not require any expertise in regulatory process. Accordingly, Defendants' reliance on Diet Drugs I and II and Rezulin is misplaced.

Defendants assert that Dr. Grimm is unqualified to opine on the prescribing habits of physicians. Contrary to Defendants' generic assaults on Dr. Grimm's qualifications, his particular experience as an eminent clinical trialist and medical educator does qualify him to opine on the prescribing habits of physicians. In deposing Dr. Grimm, Defendants did not challenge, or even probe, this area of his expertise and so did not give him an opportunity to address in detail his qualifications in the field of physician prescribing habits. These details are set forth in the accompanying Declaration of Richard H. Grimm. (Pl. Opp. Ex. 11.) Accordingly, it is more than clear that Dr. Grimm does possess "a broad range of knowledge, skills, and training" on the subject of the prescribing habits of physicians.

DSMB is involved with a clinical trial, yet OCTAVE had a DSMB in place specifically to monitor patient safety.

Finally, the opinions that Defendants seek to characterize as opinions on "ethics" are in fact opinions as to what constituted good industry practices, and what information Defendants could be expected to glean from trial data as they became known. Where Dr. Grimm makes references to Defendants' disregard for patient safety, it is to illustrate the point that there are objective ways of gauging how far Defendants departed from industry practice, and whether such departures – including their failure to recognize safety problems that could and should have been detected – were knowing.

C. The Challenged Testimony Meets the "Fit" Requirement and Should be Admitted

In addition to reliability, Rule 702 requires that the expert's testimony must assist the trier of fact in its determination of the claims and defenses. In this requirement, Rule 702 is more broadly permissive than the common law, and "expert testimony is admissible if it will simply assist the trier of fact to understand the facts already in the record, even it all it does is put those facts in context." 4 J. Weinstein & M. Berger, Weinstein's Federal Evidence, § 702.03[1], at 702-34 (2d ed. 2005). Accordingly, in entertaining Rule 702 challenges, courts are guided by a recognition that the Federal "Rules of Evidence embody a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact." Kannankeril v. Terminix Int'l Inc., 128 F.3d 802, 806 (3d Cir. 1997). See also, DeLuca by DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 956 (3d Cir.1990); Holbrook, 80 F.3d at 780.

With respect to some of the challenged testimony of both Dr. Nelson and Dr. Grimm, the challenged testimony not only "fits" the facts and theories of this case, but it is essential information for a factfinder who is charged with determining whether the statements at issue in this case were knowingly false at the time they were made or were made with reckless disregard for the truth. A plaintiff can show conscious misbehavior by adducing facts that defendants had

actual knowledge that their statements were false or misleading at the time they were made. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 238-39 (3d Cir. 2004). Recklessness can be shown by "defendants' knowledge of facts or access to information contradicting their public statements." Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000); In re Nice Sys., Ltd. Sec. Litig., 135 F. Supp. 2d 551, 585 (D.N.J. 2001) (same). A reckless statement is "a material misrepresentation or omission involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." GSC Partners, 368 F.3d at 239. "An egregious refusal to see the obvious, or investigate the doubtful, may in some cases give rise to an inference of recklessness." In re Nice Sys., 135 F. Supp. 2d at 585.

Certain of the challenged opinions are essential to Lead Plaintiff's case in that the jury would be at a loss to assess Defendants' knowing or reckless state of mind without an understanding of what industry standards are for gathering, communicating and further developing safety information in clinical trials. Dr. Nelson is an expert in the application of clinical trial safety principles within the epidemiologic, commercial and regulatory contexts in which pharmaceutical companies operate. With this expertise, he is qualified to inform the jury of the standard of ordinary care that governs the investigation into safety issues that arise from clinical data. Similarly, Dr. Grimm, with his undisputed expertise in the design, conduct and interpretation of clinical trials, is qualified to provide guidance to the jury in understanding what Defendants could and should have known and inferred from safety data, and whether the conduct of their clinical development of Vanlev represented an extreme departure from ordinary care. The testimony of both witnesses concerning these different aspects of industry standards is

essential to the factual inquiry the jury will need to conduct into whether Defendants, when making the actionable statements, displayed an extreme departure from ordinary care by disregarding adverse safety data.

As to the other opinions at issue, contrary to Defendants' assertions, the challenged testimony of Dr. Nelson and of Dr. Grimm clearly fits the facts of this case, would assist the trier of fact, and not usurp its function.

1. The Purported "Ethics" Testimony Meets the "Fit" Requirement

Defendants seek to exclude certain opinions of both Dr. Nelson and Dr. Grimm that they characterize as "Ethics" opinions. As explained at length throughout this Memorandum of Law, the so-called ethics opinions are offered to assist the trier of fact in understanding the standard of ordinary care applicable to Defendants' conduct regarding Vanlev; to the extent that usage and custom in the industry involves adherence to ethical rules, this testimony is admissible and useful to the trier of fact. See, Garcia, 996 F. Supp. at 626-27. The standard of care in an industry is an appropriate subject for expert testimony. Federal Deposit Insur. Corp. v. Refco Group, Ltd., 184 F.R.D. 623, 630 (D. Col. 1999).

The opinions of Dr. Grimm that Defendants seek to exclude here as "ethics" opinions provide the fact finder with a basis for understanding whether Defendants complied with industry standards with regard to this area of their business, and whether Defendants could reasonably have maintained their agnostic stance on Vanlev's angioedema problem if they had complied with industry standards. In short, the opinions Defendants seek to dismiss as "ethics" opinions are directly relevant to the inquiry into whether Defendants' conduct was knowing or reckless. If industry standards dictate that Defendants had a duty to "see the obvious" angioedema problem, or at least to "investigate the doubtful," before making representations that the angioedema observed with Vanlev was comparable to that seen with other ACE-inhibitors,

then their "egregious refusal" to do so is evidence of recklessness. See, In re Nice Sys., 135 F. Supp. 2d 551, 585 (D.N.J. 2001).

2. Dr. Nelson's Other Opinions Meet the "Fit" Requirement and are Needed for Rebuttal

Dr. Nelson's testimony that the FDA regulatory climate did not suddenly and dramatically change during the time period when the Vanlev NDA was under review "fits" the issues in the case, since Defendants assert the argument that there was a sea change at the FDA as a defense to allegations of scienter. In this way, Dr. Nelson's testimony fits a key question that the factfinders will have to resolve, namely, what Defendants reasonably believed about the FDA's attitudes and behavior concerning drug safety risks.[5]

In any event, the opinions Dr. Nelson offers are entirely distinguishable in nature from the opinions by the contested Diet Drugs experts which were to the effect that the defendants therein disregarded scientific standards in a bid to increase their profits. It must be borne in mind that in this respect, Dr. Nelson's testimony is in the nature of rebuttal testimony, a response to Defendants' assertion that it was impossible for them to know that the angioedema seen with Vanlev was both more frequent and more severe than that seen with ACE inhibitors. Dr. Nelson elucidates the principles whereby "safety signals" (safety data suggesting a possible problem) are identified and explored in the industry context. Without any expert guidance in how safety data are understood as they become available over time, the jury may be completely unequipped to assess whether Defendants had a reasonable basis for each of the contested statements at the time they were made.

[5] In any event, if the only person who is qualified to opine on "regulatory climate" as it relates to the Vanlev review is someone who was had specialized insider knowledge about the workings of the Cardio-Renal Division and the Vanlev review during the time period at issue, then Defendants' expert Drs. Jolson and Fredd are not qualified to opine on the regulatory climate affecting the Vanlev review.

Indeed, the testimony Dr. Nelson offers is in the same vein as the expert testimony that was challenged and upheld in Oxford Gene Tech. Ltd. v. Mergen Ltd., 345 F. Supp. 2d 431 (D.Del. 2004). In Oxford, the challenged expert was found to have specialized knowledge regarding the standard of behavior for a corporation when it is faced with an allegation of patent infringement. The court found that given her 18 years of experience in practicing law, the expert's opinion was "directly relevant to the issue of reasonable corporate behavior and her testimony [would] provide the jury with a frame of reference upon which to base its conclusions about [defendant's] behavior." Id. at 443 (internal quotations omitted). Accordingly, she was permitted to testify about the standard of reasonable commercial behavior.

Similarly, Dr. Nelson's testimony explains the usage and custom of the pharmaceutical industry with respect to identifying and analyzing drug safety issues and communicating with the FDA about those issues. Without Dr. Nelson's testimony on these points, the jury may have no basis for understanding how a reasonable pharmaceutical company behaves when the suggestion of a drug safety problem arises from a clinical database. Nor is there any merit to Defendants' claim that Dr. Nelson's testimony concerning regulatory matters (including that testimony Defendants subsume under the label "Interactions with the FDA") invades the province of the jury. Dr. Nelson's testimony in this regard is of exactly the same nature as the "testimony regarding the applicable standard of care for reporting adverse drug events" that was held useful to the jury in another matter involving drug safety. Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684, 700 (W.D.N.C. 2003).

3. Dr. Grimm's Other Testimony Meets the "Fit" Requirement

Defendants challenge Dr. Grimm's so-called "ethics" testimony on grounds of fit. The opinions Defendants lump under this misleading heading in fact relate to standards of reasonable conduct for a pharmaceutical company engaged in drug development. The challenged testimony

relates to BMS's less than candid filings and other communications with the FDA concerning the incidence and severity of angioedema in the Vanlev clinical trials.

Accordingly, it is self-evident that such testimony will assist the trier of fact: as to the First Class Period, Lead Plaintiff contends that Defendants knew or should have known that it was reckless to make glowing statements that Vanlev was a safe drug, given the state of information about Vanlev; incidence and severity of angioedema, whereas Defendants rejoin that they did not know and could not have known that there was a safety problem with Vanlev until the FDA raised the issue in March 2000. Had BMS been more forthright with the FDA, it is reasonable to conclude that the FDA would have voiced its concerns sooner.

Lead Plaintiff also contends that in view of the trial design and the data that ultimately emerged from OCTAVE, Defendants knew or should have known that Vanlev could not be approved for the treatment of broad hypertension, whereas Defendants counter that they reasonably believed they could still have proved the advantages of the drug. Accordingly, not only do Dr. Grimm's opinions with respect to these questions "fit" the case, but in the absence of his testimony, the jury would be unable to reach intelligent conclusions about the drug's safety and, concomitantly, its prospects for approval following OCTAVE.

D. The Challenged Testimony Meets the Standard for Reliability

The essential guidance learned from Daubert, Kumho Tire and Joiner is that an expert's testimony must be based upon sufficient facts and flow from the reliable application of sound reasoning or methods. Fed. R. Evid. 702. Here, all of the challenged testimony is reliable.

1. Dr. Nelson's Testimony is Reliable

(a) Dr. Nelson's Opinions Concerning What BMS Should Have Known are Reliable

Defendants assail as unreliable the opinions Dr. Nelson has offered concerning what BMS knew or should have known about Vanlev's risks, applicable regulatory and industry standards, and BMS's adherence to or deviation from those standards. In attacking the opinions, Defendants misleadingly characterize them as testimony regarding "State of Mind," "BMS's Interactions With The FDA" and "Ethics." The basis for Defendants' challenge to the reliability of these opinions is Dr. Nelson's purported lack of qualification to render them. As set forth at length above, Dr. Nelson is fully qualified to render each of the challenged opinions, and each of them has a sound basis in fact and in this expert's knowledge and experience.

Dr. Nelson's very expertise in the ethical dimensions of regulatory science make his challenged opinions all the more reliable. See, Hall v. Babcock & Wilcox Co., 69 F. Supp. 2d 716, 725 (W.D. Pa. 1999) (finding that expert witness was qualified to testify as to causation issues regarding radiation and the incidence of cancer, where expert had "testified before Congress on the issue of medical ethics and corporate responsibility concerning the use of radiation and radioactive materials." See also, Wetherill v. University of Chicago, 565 F. Supp. 1553, 1564 (N.D. Ill. 1983) (where expert witness was an Associate Professor of Ethics in the University of Illinois Department of Internal Medicine, and had written extensively in the field of medical ethics and experimentation, he "certainly has the qualifications to testify as to prevalent disclosure policies," [i.e. informed consent standards]).

(b) Dr. Nelson's Evaluations of Vanlev's Probability of Attaining Regulatory Approval are Sound

Defendants contend, without benefit of supporting authority, that there is an "accepted methodology" that Dr. Nelson ought to have employed, of "systematically reviewing all the data in an NDA about a drug and analyzing the drug's benefits and risks." (Def. Mem. at 20.) Of course, not one of Defendants' experts systematically reviewed all the data in either the first or

the second Vanlev NDA. Accordingly, if Dr. Nelson's opinions are to be rejected on this ground, then all the opinions of all Defendants' experts must likewise be rejected. In any event, Defendants' position in this regard is utterly fallacious. Dr. Nelson's report and testimony explain at great length the basis for Dr. Nelson's opinion that the "benefit" element of Vanlev's "risk/benefit" profile was not at issue, because the drug's efficacy as a blood-pressure lowering agent had been established, but it had no other demonstrated benefits in terms of morbidity or mortality. (See, e.g., PX 16 61.) Accordingly, given the standard for hypertensive drugs, the only benefit at issue was that Vanlev effectively lowered blood pressure. Dr. Nelson's contention that only the "risk" part of the "risk/benefit" equation would affect the regulatory decision is one that he has explained and defended. In fact, references throughout Dr. Nelson's report to Vanlev's efficacy, and to the drug's risk/benefit profile are so numerous that they cannot be recited here.

The standard of reliability is not a "correctness" standard, and indeed the Third Circuit has taken pains to point out that "the standard for determining scientific reliability 'is not that high.'" Oddi v. Ford Motor Co., 234 F.3d 136, 156 (3d Cir. 2000) (citing Paoli II, 35 F.3d at 744-45). Even if the standard held up as "correct" by Defendants (on no more than the ipse dixit of counsel) were in fact a "correct" one, that would not render Dr. Nelson's approach "incorrect" or unreliable. Defendants take a contrary position, and it will be up to a jury to decide whether or not Dr. Nelson's view is the better one. But Dr. Nelson's approach of acknowledging Vanlev's proven efficacy and then assessing the drug's prospects only with reference to its troublesome safety characteristics is fully explained and internally consistent. Accordingly, each of Dr. Nelson's opinions assessing Vanlev's likelihood of attaining regulatory approval is reliable.

2. Dr. Grimm's Testimony is Reliable

Defendants' arguments assailing the reliability of Dr. Grimm's testimony are based upon either a mischaracterization of the challenged opinions or an outright misrepresentation of his qualifications.

There is a reliable basis for the challenged statement in Dr. Grimm's report to the effect that if FDA had known of the seriousness of angioedema with Vanlev in the First Class Period, it could and would have intervened. His testimony at deposition, to the effect that it is impossible to know which of its mechanisms the FDA may invoke to respond to a particular safety concern in a particular clinical program, is not symptomatic of an absence of reliable methodology. Rather, Dr. Grimm was acknowledging that the FDA has a variety of means at its disposal, and it may have a number of available options to accomplish the same objective. This testimony is entirely consistent with the testimony of both percipient and expert witnesses on both sides throughout these proceedings.

As an expert in designing and conducting clinical trials, Dr. Grimm reviewed the OCTAVE protocol, safety data and other related documents, and concluded that based upon the OCTAVE safety data, Vanlev would not be approved as a treatment for general hypertension. In order to reach this conclusion, it was not necessary for Dr. Grimm to be familiar with the NDA review process; instead, he relied on his knowledge and understanding of clinical trials and his experience in the risks and benefits of balancing of antihypertensive medications. The reasoning underlying his challenged opinion, that Vanlev would not be approved for broad hypertension following OCTAVE, is that the OCTAVE trial was designed for the purpose of assessing Vanlev's safety; the trial protocol set a benchmark for an acceptable incidence of angioedema; and the trial data proved that Vanlev did not have an acceptable safety profile.

Like Dr. Nelson, Dr. Grimm understood that only by changing the "risk" element of Vanlev's "risk/benefit" picture could OCTAVE change Vanlev's regulatory fate. Because OCTAVE demonstrated that Vanlev could not be taken safely as a treatment for general hypertension, it could not overcome the barrier to approval. Dr. Grimm, as acknowledged by Defendants' expert, is one of the world's leading experts on the link between blood pressure reduction and reduction in mortality. Accordingly, he is fully cognizant of the merits of Vanlev's efficacy data. Dr. Grimm's rejection of Defendants' claim that the efficacy data from OCTAVE might have proven that the benefits of the drug outweighs its risks, is based upon his eminent qualifications and expertise in this specialized area of cardiovascular medicine. Nothing in Rule 702 "suggests that experience alone – or experience in conjunction with other knowledge, skill, training or education – may not provide a reliable basis for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience." Fed. R. Evid. 702 Advisory Committee Notes; accord, Kumho Tire Co. v. Carmichael, 526 U.S. 137, 156 (1999). Accordingly, Dr. Grimm's analysis is reliable by virtue of his extensive experience.

As discussed at some length above, the opinions Defendants seek to frame as "ethics" opinions are, in fact, opinions as to the applicable standards of good industry practice with respect to safety monitoring in drug trials. Defendants do not contest the reliability of the so-called "ethics" opinions. Nevertheless, it should be noted that as an eminent clinical trialist, Dr. Grimm has applied to his analysis the same standards he applies every day in carrying out drug research in human subjects, whether for NIH-funded or industry-funded studies. These opinions are therefore reliable.

Having failed to probe Dr. Grimm's qualifications to opine on physicians' prescribing habits, Defendants are content to cast the opinions as "speculation" and therefore unreliable. As set forth in Dr. Grimm's declaration, he has substantial experience and knowledge concerning prescribing habits, so Defendants' assault on the opinions as speculation misses the mark entirely. It should further be noted that the challenged opinions concerning doctors' likelihood to prescribe and to titrate Vanlev should it be approved under various conditions is not at all like the challenged opinions the Rezulin court rejected. The proffered experts in Rezulin sought to opine on how or whether physicians would read a drug label and how they would understand the language contained therein. Rezulin, 309 F. Supp. 2d at 556. Indeed, it would be difficult to reach meaningful conclusions on these questions absent a systematic inquiry. In contrast, Dr. Grimm's knowledge about prescribing habits is gleaned, inter alia, from the conduct of investigators in literally scores of clinical trials with which Dr. Grimm has been involved, years of constant engagement with doctors under his oversight or seeking professional guidance from him in treatment strategies.

III. The Challenged Testimony is not Confusing or Prejudicial

Defendants' assertions that Dr. Nelson's and Dr. Grimm's testimony are "confusing and prejudicial" are pro forma and utterly lacking in substance. In any event, the challenged testimony is neither confusing nor prejudicial, and is essential to guide the jury in understanding whether Defendants had a reasonable basis for believing the statements at issue in this case were true. It is well settled that expert testimony on the ordinary practices of a profession or trade is appropriate "to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry." Rezulin, 309 F. Supp. 2d at 543 (quoting Marx & Co. v. Diners' Club Inc., 550 F.2d 505, 509-10 (2d Cir. 1977) (internal citation omitted).

Insofar as they cite Rezulin as support for their argument that the proffered testimony concerning industry practice is irrelevant and more prejudicial than probative, Defendants' reliance on that case is misplaced. In Rezulin, a products liability case brought by against the manufacturer of the diabetes drug Rezulin by persons who allegedly developed liver failure as a result of the drug, plaintiffs sought to introduce expert testimony that the drug manufacturer acted in an unethical manner in conducting the Rezulin clinical trials. The court excluded the testimony for reasons that are not applicable here.

First, the issue for the trier of fact in Rezulin was whether defendants had breached their legal duties in manufacturing, labeling and marketing the drug. Rezulin, 309 F. Supp. 2d at 544. The Court found that under those facts, expert opinion as to the ethics of defendants' actions was irrelevant. There is no scienter requirement in a products liability action. Here, in contrast, Dr. Nelson's and Dr. Grimm's expert opinions on industry standards are critical in guiding the jury in its assessment of whether their conduct in carrying out the Vanlev clinical trials was such an extreme departure from the standards of ordinary care as to give rise to an inference of recklessness. See, In re Nice Sys., 135 F. Supp. 2d at 585.

Second, the expert witnesses in Rezulin admitted that their opinions concerning proposed ethical standards were based not on any expertise, but on their own personal subjective views. The Court found that their opinions did not mean the core requirement that expert testimony rest on "knowledge." 309 F. Supp. 2d at 543. Here by contrast, as set forth at length in Points II.A. and II.B., supra, both Dr. Nelson and Dr. Grimm are experts in fields relating to human subject research, in which clearly prescribed ethical standards are at the core of industry usage and custom. Unlike the testimony about ethics in Rezulin, the testimony of both these witnesses about industry standards is firmly rooted in specialized knowledge.

The decision in Diet Drugs II, 2001 WL 454586, at *9, is similar to Rezulin, and not applicable here. The pertinent issues in Diet Drugs II were the obligations of a pharmaceutical company in testing, surveying and labeling medications. The court excluded plaintiffs' expert testimony about medical ethics for the same reasons as did the Rezulin court: medical ethics were not probative of the issues in the case, and the witness did not have sufficient knowledge to qualify him to opine on medical ethics of pharmaceutical companies. The court noted that pharmaceutical company conduct is governed by extensive regulations of which the expert had little or no knowledge, and that the expert lacked experience with FDA regulations. In this case, by contrast, Dr. Nelson has extensive knowledge of pharmaceutical company conduct as well as extensive, directly relevant, FDA experience. Dr. Grimm, while not a regulatory specialist, is so expert as a clinical trialist that he is qualified to render an opinion about the mandatory ethical precepts that govern the conduct of clinical trials.

Neither Dr. Nelson's nor Dr. Grimm's is offered for the proposition that Defendants engaged in unethical conduct in carrying out their clinical trials and they are therefore liability for securities fraud. Rather, the testimony goes solely to the question of whether Defendants' extreme departure from industry usage and custom, including but not limited to the ethical precepts of clinical trials, gives rise to an inference of recklessness. Such testimony should not be excluded under Rule 403, even if breach of an ethical duty is not a cause of action, because the testimony goes to standard of care. Garcia, 996 F. Supp. at 626-27. Accordingly, Rezulin and Diet Drugs are inapposite. If the Court is concerned that use of the word "ethics" will be prejudicial, counsel and the witnesses can easily be directed not to use the word.

Additionally, it would be contrary to Third Circuit standards for the Court to reject Dr. Nelson's or Dr. Grimm's testimony at this stage on Rule 403 grounds. When balancing the

considerations of the admissibility of expert testimony under Rule 702 against the Rule 403 consideration whether admitting the evidence would overwhelm, confuse or mislead the jury, the Third Circuit recognizes a presumption of helpfulness of the expert testimony. See, Paoli II, 35 F.3d at 746. The court emphasized that in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue. The Paoli II court also noted that the fact that Daubert held that Rule 702 is the primary locus of a court's gatekeeping role indicates that exclusion under Rule 403 should be rare. Paoli II, 35 F.3d n. 16. To the extent that an adverse party has had notice and the opportunity to present his or her own experts, it is even less reasonable to exclude expert testimony on Rule 403 grounds at the Daubert stage. Id.

Finally, recapitulating its earlier holding in Paoli I, 916 F.2d at 829, the Paoli II court noted that "Rule 403 is rarely appropriate as a basis of *pre-trial* exclusion, because a judge cannot ascertain potential relevance until that judge has a virtual surrogate for a trial record." Paoli II, 35 F.3d at 747. In Paoli I, the court said in the context of considering motions to exclude experts' testimony under Rule 403: "[W]e stress that *pretrial* Rule 403 exclusions should rarely be granted.… [If] testimony survives the rigors of Rule 702 and 703 … Rule 403 is an unlikely basis for exclusion. Excluding evidence as being more prejudicial than probative at the pretrial stage is an extreme measure that is rarely necessary, because no harm is done by admitting it at that stage." Paoli I, 916 F.2d at 859 (internal quotations omitted). In view of this standard, there is no reason for the court to invoke the extreme measure of excluding Dr. Nelson's or Dr. Grimm's testimony on Rule 403 grounds at this time.

As the Court noted in Daubert, 509 U.S. at 596, vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and

appropriate ways of challenging evidence. All of those means are available to defendants. The extreme sanction of excluding expert testimony is neither necessary nor warranted in the case of Dr. Stolley. See also, 4 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence, § 702.02[5] (Matthew Bender 2d ed. 2005) "[M]any courts considering challenges to potentially confusing expert testimony under Rule 702 hold that , if the risk of confusion is not great, the potentially confusing nature of the testimony goes to the weight to be accorded to the evidence, and the proper course is to admit the expert testimony and leave clarification to cross examination and the presentation of opposing expert testimony."[6]

CONCLUSION

For the reasons set forth above, Lead Plaintiff respectfully requests that the Court deny Defendants' motion to strike the testimony of Dr. Nelson and Dr. Grimm.

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[6] The opinions offered by Dr. Nelson – on regulatory science, regulatory process, drug safety and other issues – and by Dr. Grimm – on good clinical trial practice, and practical issues in clinical cardiology, like doctors' prescribing and treating habits – are unique to that expert's report. There is accordingly no reason to exclude any part of either of these experts' reports or testimony as cumulative of other evidence.

APPENDIX A

Summary of Dr. Nelson's Opinions*	**Pages**
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Opinions Concerning Measures Defendants Were Required To Take When It Began Clinical Development, Given Their Knowledge Of Vanlev's Likely Safety Risks	5-9
Opinions Concerning The Relationship Between Vanlev's Safety Profile And Defendants' Expressed Intentions Concerning Commercialization Of Vanlev	28
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Opinions Concerning BMS' Failure To Raise Angioedema Concerns With the FDA During the Phase II Trials As A Departure From the Standard of Ordinary Care	27-29
Opinions Concerning BMS' Failure To Conduct An Epidemiology Analysis As A Departure From the Standard of Ordinary Care	29-33
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Opinions Concerning The Phases Of Drug Development and Industry Usage and Custom With Respect Thereto	27-29; 58

* This chart does not purport to be a comprehensive list of Dr. Nelson's opinions, some of which are multifaceted, and many of which are touched upon on other pages in addition to those referenced. Nevertheless, this chart provides a more accurate representation of the nature and scope of Dr. Nelson's expert testimony than does the Defendants' Memorandum of Law.

Summary of Dr. Nelson's Opinions*	**Pages**
Opinions Concerning BMS' Failure to Adequately Disclose the Serious Angioedema in The Fall 1999 Safety Update, And Its Failure To File An Expedited Report At That Time, As Departures From the Standard of Ordinary Care	50-52
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